

**REMARKS**

In the Office Action mailed March 28, 2006 the Examiner stated:

This application contains claims directed to the following patentably distinct species: Species I in figures 1a,b; Species II in figure 2 and Species III in figure 3. The species are independent or distinct because of the different embodiments connected to an endoscope.

Under 35 USC 121 the Examiner required the Applicants to elected a single disclosed species for prosecution on the merits. The examiner also advised the Applicants that, “the reply to the restriction requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.”

The restriction requirement imposed by the examiner is unclear, as will be explained below. Accordingly the Applicants are uncertain how to respond to the restriction requirement. Applicants respectfully request that the Examiner withdraw her restriction requirement and impose the following:

Species I corresponding to Claims 1-17 and 32-64, which are apparatus claims.

Species II corresponding to Claims 18-31, which are method claims.

If the Examiner were to do so, the Applicants would elect Species I, Claims 1-17 and 32-64. However, if the Examiner is not willing to amend her restriction requirement the Applicants hereby elect Claims 1-17 with traverse. As best Applicants can understand the examiner's restriction requirement these claims appear to correspond to the Examiner's alleged Species I.

**Traverse**

The Restriction Requirement is not proper for two reasons. First, it is not clear, and

second it is improperly based on figures rather than claims.

**Restriction requirements must be clear**

There can be no doubt that restriction requirements must be clear. For example, MPEP §809.02(a) requires the examiner to, “Clearly identify each (or in aggravated cases at least exemplary ones) of the disclosed species, to which claims are restricted.” Moreover, the heading of MPEP §814 enjoins the examiner to “Indicate Exactly How Application Is To Be Restricted.”

There are many reasons for the requirement of clarity. For example, if a restriction requirement has been imposed and thereafter an applicant files a divisional application, 35 USC §121 provides, in relevant part:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

The Court of Appeals for the Federal Circuit has explained that 35 U.S.C. §121 will not apply to remove the parent as a reference where the principle of consonance is violated:

“Consonance requires that the line of demarcation between the “independent and distinct inventions” that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.” Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 688, 16 U.S.P.Q.2d (BNA) 1436, 1440 (Fed. Cir. 1990).

In the case of Geneva Pharmaceuticals, Inc., V. Glaxosmithkline Plc et al., 349 F.3d 1373; 2003 U.S. App. LEXIS 23795; 68 U.S.P.Q.2D (BNA) 186 (Fed Cir. 2003) the Court of Appeals for the Federal Circuit emphasized the importance of clarity in restriction requirements.

Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement. Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1579 (Fed. Cir. 1991) ("Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained . . . . Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.") (quoting Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990)). If a restriction requirement does not clearly set forth the line of demarcation, then challenged claims could not satisfy the consonance requirement. Therefore restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of §121's protections. 349 F.3d 1373, 1381, emphasis added.

Turning now to the present case, the Applicants respectfully point out that the restriction requirement is unclear in a number of respects. The following are some examples.

The Examiner has not indicated any alleged species which correspond to Figures 4 or 5. This makes no sense. Figure 4 simply shows the device illustrated in other figures as it is used in a patient. Figure 5 illustrates steps of the claimed process. By not associating Figure 5 with any "species" is the Examiner suggesting that the Applicants may not elect method claims?

As another example of the lack of clarity in the restriction requirement, the Examiner indicates that Species I corresponds to Figures 1a, b while Species I I corresponds to Figure 2. However, some of Applicants' claims, e.g. Claim 1, read on all three Figures. Therefore if, for example, the Applicants were to elect Species I and state that Claim 1 reads on Species I could Applicants thereafter file a divisional application and elect species II and again prosecute Claim 1 in the divisional application?

As still another example of the lack of clarity in the restriction requirement, the Examiner indicates that Species I corresponds to Figures 1a, b while Species III corresponds to Figure 3. However, some of Applicants' claims, e.g. Claim 1, read on all three Figures. Therefore if, for example, the Applicants were to elect Species I and state that Claim 1 reads on Species I could Applicants thereafter file a divisional application and elect species III and again prosecute Claim 1 in the divisional application?

**A restriction requirement must be based on claims, not on figures**

The statutory basis for restriction requirements refers to **claims**, not figures. "If two or more independent and distinct inventions are **claimed** in one application, the Director may require the application to be restricted to one of the inventions." 35 USC §121 (emphasis added.)

Furthermore, the Manual of Patent Examining Procedure (MPEP) does not allow the restriction requirement imposed by the Examiner. The MPEP requires that an Examiner must base a restriction requirement on the **claims**, not the figures in an application.

The MPEP clearly requires an Examiner to base a restriction on the **claims**. There are many examples of this throughout Chapter 800, which governs restriction practice, and some of the most prominent are recited below.

"In passing upon questions of double patenting and restriction, it is the **claimed** subject matter that is considered and such **claimed** subject matter must be compared in order to determine the question of distinctness and independence." MPEP § 806.01.

"Where the **claims** of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required." MPEP § 806.03.

“Where an applicant files a divisional application claiming species **claimed** but not elected in the parent case . . .there should be no determination of whether or not the species **claimed** in the divisional is patentable over the species retained in the parent case since that determination was made before the requirement to restrict was made. . . . “[T]he Examiner should not require restriction to a reasonable number of species unless he or she is satisfied that he or she would be prepared to allow **claims** to each of the **claimed** species over the parent case, if presented in a divisional application. . . .” MPEP § 806.04(h).

The form Outline of Letter for Restriction requires the Examiner to, “List **claims** in each group.” MPEP § 817 Outline of Letter (a)(2).

### CONCLUSION

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Please charge any additional required fee or credit any overpayment not otherwise paid or credited to our deposit account No. 50-1698.

Respectfully submitted,  
THELEN REID & PRIEST LLP

Dated: 7/6/06

  
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